IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

ALVOTECH USA INC. and ALVOTECH HF., Plaintiffs, v. ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD, Defendants.	C.A. No. 2:21-cv-265-RAJ-DEM

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS OR, IN THE ALTERNATIVE, TO TRANSFER

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

OTHER AUTHORITIES

I. INTRODUCTION

This ***second-filed*** lawsuit concerns ***the same patents, same product, and same issues*** as a lawsuit filed two weeks earlier in the Northern District of Illinois by AbbVie Inc. ("AbbVie"), which is headquartered in Illinois, against Alvotech hf. ("Alvotech"), an Icelandic company. AbbVie markets the highly successful drug HUMIRA®, which has transformed the lives of over a million patients suffering from autoimmune disorders such as rheumatoid arthritis and Crohn's Disease. AbbVie sued Alvotech for patent infringement in AbbVie's home state of Illinois because Alvotech has developed, manufactured, and sought regulatory approval for a "biosimilar" version (essentially a copy) of HUMIRA® in the United States. This is Alvotech's retaliatory suit, which belongs in Illinois as compulsory counterclaims to AbbVie's suit.

Forum shopping in federal court, by responding to a lawsuit in one jurisdiction with a second, essentially identical suit elsewhere, is highly discouraged. When it happens, the "first-to-file rule" creates a strong presumption that the first suit should go forward and the second should be dismissed or transferred to the first court. That is the case here.

Alvotech's complaint attempts to excuse its improper forum shopping by alleging that the Illinois suit is missing a necessary party over which that court lacks jurisdiction. That is factually and legally wrong, but in any event, the proper way to resolve that issue would be via a motion to dismiss ***in Illinois***. Yet, five weeks into that case, Alvotech has yet to file any such motion. And for good reason. Under controlling law, AbbVie properly filed suit in its home forum against a foreign competitor seeking to sell a copy of its drug in the forum state and throughout the country. Indeed, it was the most logical and appropriate place for AbbVie to do so.

Moreover, this case has no meaningful connection to this District, much less one that would trump the first-to-file rule. Alvotech's sole alleged connection to Virginia is its wholly owned subsidiary, Alvotech USA. But whereas Alvotech has allegedly been working on biosimilar

HUMIRA® since 2013, Alvotech USA did not even ***exist*** until 2019, and has only a handful of employees today. According to Alvotech's website and its pleading, Alvotech USA is not involved in developing, making, or marketing drugs; it serves only legal and regulatory functions. The true party in interest is Alvotech, which developed, manufactured, and seeks permission from the FDA to market its biosimilar HUMIRA®. There is no reason to depart from the first-to-file rule.

Moreover, this Court lacks personal jurisdiction over the AbbVie parties, which lack any meaningful contacts with Virginia. Alvotech asserts otherwise, because AbbVie responded to correspondence Alvotech sent to AbbVie (in Illinois); participated in the statutorily required "patent dance"; and applied for patents at the Patent Office. None of these theories holds water. Nor do Federal Rule of Civil Procedure 4(k)(2) or 35 U.S.C. § 293 apply, as they are meant for parties not otherwise subject to jurisdiction in the United States. While defendant AbbVie Biotechnology Ltd (ABL) (AbbVie's wholly-owned subsidiary) is incorporated in Bermuda, it is subject to jurisdiction in Illinois, having sued Alvotech there for infringing the same four patents, and through business arrangements and exclusive licensing of these patents to AbbVie.

Finally, if it reaches this issue, this Court should transfer this case under 28 U.S.C. § 1404 to the Northern District of Illinois. Illinois is a more efficient venue, not only because of pendency of the first suit, but also an additional suit involving the same product and related patents. The convenience factors favor Illinois as well. After all, AbbVie is headquartered in North Chicago, and many of the witnesses and documents are there. Essentially none are here.

That said, the Court need not reach the jurisdiction or Section 1404 issues. This case can and should be readily disposed of under the first-to-file rule.

II. BACKGROUND

A. AbbVie and HUMIRA®

AbbVie is one of the leading pharmaceutical companies in the world, and produces medicines to treat a wide range of diseases, including cancers, infectious diseases, and autoimmune disorders. AbbVie employs over 10,000 people in Illinois, nearly all of whom work at AbbVie's main campus and two additional locations in the North Chicago area. Ranganathan Decl. ¶ 9.[1] ABL, a wholly-owned subsidiary of AbbVie, owns the patents-in-suit, but exclusively licenses them to AbbVie. *Id*. at ¶ 14. ABL also manufactures the active ingredient in HUMIRA®, which is sent to AbbVie in North Chicago for final packaging before shipping to customers. *Id.* at ¶ 15.

In 1996, AbbVie's predecessor invented adalimumab, the active ingredient in HUMIRA®. But that was only the first step. Over the next 25 years, AbbVie spent hundreds of millions of dollars in research and development on HUMIRA®, developing new and improved formulations, conducting more than 100 clinical trials to discover new uses for the drug, and developing innovative manufacturing processes. *Id.* at ¶ 11. AbbVie continues to innovate HUMIRA® to this day: just this year, the FDA approved a new indication for children suffering from ulcerative colitis. Ex. 1; Ranganathan Decl. ¶ 12.[2]

AbbVie's decades of investment and research have resulted in a robust IP portfolio. Alvotech seeks to disparage AbbVie's patent portfolio, but its rhetoric is belied by the facts. That said despite vigorously disagreeing with Alvotech's allegations, AbbVie will reserve its substantive response for the proper time and focus here on the procedural issues relevant to this

[1] "Ranganathan Decl." refers to the Declaration of Sowmyan Ranganathan, submitted in support of AbbVie's motion.

[2] "Ex. __" refers to the Exhibits attached to the Declaration of Herman H. Yue ("Yue Decl."), submitted in support of AbbVie's motion.

motion. Suffice it to say that some of the most sophisticated pharmaceutical companies in the world—Amgen, Pfizer, and Sandoz—have taken a license or settled after challenging AbbVie's patents. Exs. 2-4. A number of these companies sought to invalidate AbbVie's patents in *Inter Partes Review* ("IPR") proceedings before the U.S. Patent Office, but the vast majority were rejected. Indeed, of the 20 IPR petitions brought against the HUMIRA® patent estate, two-thirds (13 of the 20) were not even ***initiated***, meaning the challenger failed to show that even a ***single claim*** was likely invalid, despite the lower burden of proof in those proceedings.[3] Ex. 5. In short, AbbVie's patent estate is robust, and has survived many a battle, from some of the top companies and law firms in the world.

B. Alvotech

Alvotech is an Icelandic company focused on developing biosimilars (essentially generic copies of biologic drugs). Dkt. 1 at ¶ 18. Since 2013, Alvotech has been developing AVT02, a biosimilar version of HUMIRA®. *Id.* at ¶ 14. For at least six years, Alvotech was the sole entity working on AVT02: directing clinical trials; meeting with the FDA; and preparing, creating, approving and/or assembling the documentation in support of Alvotech's abbreviated Biologics Licensing Application ("aBLA") for AVT02. *Cf. id. with* Ex. 6.

Only in 2019, during the final stages of AVT02's development, did Alvotech form Alvotech USA, a wholly-owned subsidiary with only a handful of employees in Arlington, Virginia. Ex. 8. Unlike Alvotech, Alvotech USA is limited to handling "legal, governmental policy, and regulatory affairs," with no role in AVT02 development, manufacturing, or sales or in

[3] Whereas establishing patent invalidity in district court requires clear and convincing evidence, the burden in IPRs is a mere preponderance of the evidence.

generating the data and information necessary for submission and approval by the FDA. Dkt. 1 at ¶ 21.

On November 5, 2020, Alvotech informed AbbVie that it had submitted its aBLA to the FDA, seeking approval to commercialize AVT02. Yue Decl. ¶ 12. While Alvotech USA may have licked the stamp, it was Alvotech, its Icelandic parent, that was solely responsible for the development of AVT02 and will be solely responsible for its manufacture. Dkt. 1 at ¶¶ 20, 22; Ex. 7 ("Under this partnership agreement [with Teva], Alvotech will be responsible for the development, registration and supply of the biosimilars, while Teva will be exclusively commercializing the products in the U.S."). Alvotech sponsored, and continues to sponsor, direct, and authorize clinical trials for AVT02. *See* Exs. 9-14. And Alvotech, not Alvotech USA, will profit from the sales of AVT02 as part of its "exclusive strategic partnership [with Teva] for the commercialization [of AVT02] in the U.S.," under which Alvotech will manufacture the drug and share in the profits from U.S. sales. *See* Ex. 7. Notably, and consistent with its limited responsibilities, no role has been announced for Alvotech USA marketing or selling AVT02. *See* Ex. 15; Dkt. 1 at ¶ 21.

C. BPCIA and AbbVie's First Suit in the Northern District of Illinois

Unlike traditional drugs, biologics are medicines generally made by genetic engineering. In 2009, Congress enacted the Biosimilar Price Competition and Innovation Act of 2009 ("BPCIA") which provides an abbreviated pathway for approval of biologics that are "biosimilar" to "reference products" like HUMIRA®. *See* 42 U.S.C. § 262. This process is analogous to the so-called "Hatch-Waxman" regulatory pathway for generic drugs. Both allow a generic (or biosimilar) drug manufacturer to utilize an abbreviated testing and clinical trial process, skipping the extensive testing and human trials required for the initial, innovative product. Under the BPCIA, the biosimilar company piggybacks on the innovator's hard work.

Anticipating that biologics would be subject to extensive patent protection, Congress set forth a highly choreographed process for the biosimilar applicant and innovator to exchange information, after which the innovator sues for patent infringement. 42 U.S.C. § 262(*l*)(2)-(3). The process, often referred to as the "patent dance," begins when the biosimilar applicant submits an aBLA (containing information about the drug, its use, and how it is made and tested) and the FDA accepts it for review. The biosimilar applicant then provides the innovator, termed the "reference product sponsor" (here, AbbVie), a copy of its aBLA and additional information describing its manufacturing process. 42 U.S.C. § 262(*l*)(2).

After review of the aBLA, the reference product sponsor provides a list of patents it believes may be infringed based on the information provided, and the parties exchange positions on the infringement and validity of those patents. 42 U.S.C. § 262(*l*)(3)(A)-(C). Once those exchanges are complete, the parties discuss the number and identity of the patents to be included in a first phase of litigation. 42 U.S.C. § 262(*l*)(4). The biosimilar applicant, however, ultimately controls the number of patents litigated during this initial phase. *Id.* The reference product sponsor is then required to bring suit on the selected patents within 30 days.

Here, AbbVie and Alvotech engaged in the "patent dance" over the course of nearly six months. Alvotech could have chosen to litigate all 62 patents identified by AbbVie, but it chose only four. Yue Decl. ¶ 3. Based on Alvotech's patent selection, AbbVie sued Alvotech on April 27, 2021, in the Northern District of Illinois under 35 U.S.C. § 271(e)(2), alleging that AVT02 infringed those four patents. *See AbbVie Inc. v. Alvotech hf.*, C.A. No. 21-cv-2258 (N.D. Ill.); Ex. 16. Two of those patents, U.S. Patent Nos. 8,420,081 and 9,085,619 are directed to novel, high concentration formulations of HUMIRA® that cause less pain when injected by patients. Dkts. 1-2 and 1-3. The others are directed to novel treatment methods: one for ankylosing spondylitis, a

debilitating disease that results in fusion of the spinal vertebrae (U.S. Pat. No. 8,926,975, Dkt. 1-4); and the other for Crohn's Disease, an autoimmune disorder of the digestive tract (U.S. Pat. No. 8,961,973, Dtk. 1-5). Like many of AbbVie's other patents, the patents-in-suit have been battle tested. For example, the ***Patent Office has rejected four separate IPR petitions*** challenging the validity of the '619 patent, and another challenging a patent related to the '973 patent. Ex. 5.

The Illinois case has been pending for five weeks, but Alvotech has yet to file a responsive pleading or motion, despite entering appearances for five attorneys from two major law firms.

D. The Present Suit

On May 11, 2021, two weeks after AbbVie filed its Illinois lawsuit, Alvotech filed this suit on ***the same patents, product, and issues***. *See* Dkt. 1. The result is two lawsuits pending in two federal courts involving identical issues: AbbVie's first suit in Illinois, and Alvotech's second suit here.

E. AbbVie's Second Suit in the Northern District of Illinois

Under the BPCIA, a biosimilar must give the reference product sponsor at least 180 days' notice before launching its product, so the reference product sponsor has time to seek an injunction if the biosimilar is infringing its patents. This notice also triggers the opportunity for the reference product sponsor to sue on any patents not included in the original litigation between the parties. On May 11, 2021, Alvotech notified AbbVie of its intent to begin marketing AVT02 in 180 days.[4] AbbVie consequently filed a second lawsuit in the Northern District of Illinois on the remaining 58 patents identified during the patent dance. *AbbVie Inc. v. Alvotech hf.*, C.A. No. 21-cv-2899 (N.D. Ill.). Because it is closely related to the first suit—same parties, same product, and numerous

[4] While filing this notice would theoretically allow Alvotech to try to market AVT02 in just 180 days, it does not appear Alvotech provided notice for that reason, since Alvotech's CEO recently announced his goal to be on market within ***two years***. Ex. 17.

related patents—AbbVie will ask that it be reassigned from another judge (to whom it was randomly assigned) to Judge Lee.

III. ARGUMENT

A. This Action Should Be Dismissed or Transferred Under the First-to-File Rule

This is the second-filed case involving overlapping parties and identical patents, product, and issues. As such, it should be dismissed or transferred to Illinois, where the first case is pending, under the first-to-file rule and principles of federal comity. *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012) ("The 'first-to-file' rule is a doctrine of federal comity, intended to avoid conflicting decisions and promote judicial efficiency, that generally favors pursuing only the first-filed action when multiple lawsuits involving the same claims are filed in different jurisdictions."). Federal Circuit, rather than Fourth Circuit, law governs because patent infringement defendants have tried previously to use the declaratory judgment act to effect a change in litigation forum. *Futurewei Techs., Inc. v. Acacia Rsch. Corp.* , 737 F.3d 704, 708 (Fed. Cir. 2013) ("Resolution of whether the second-filed action should proceed presents a question sufficiently tied to patent law that the question is governed by [Federal Circuit] law.") (quoting *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1347 (Fed. Cir. 2005)). And the Federal Circuit has spoken clearly: "When two actions that sufficiently overlap are filed in different federal district courts, one for infringement and the other for declaratory relief, ***the declaratory judgment action, if filed later, generally is to be stayed, dismissed, or transferred to the forum of the infringement action***." *Id.* (citing *Merial*, 681 F.3d at 1299); *see also Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 938 (Fed. Cir. 1993) ("[I]n patent cases the general rule" is that "the first-filed case is favored, unless considerations of judicial and litigant economy, and the just and effective disposition of disputes, require otherwise."), *rev'd on other grounds*, *Wilton v. Seven Falls Co.*, 515 U.S. 277

(1995). The Federal Circuit's rule is consistent with the general rule—and Fourth Circuit application thereof—providing a strong presumption of priority to the first-filed action when two suits are the same or have overlapping claims. *Merial*, 681 F.3d at 1299 ("When two courts have concurrent jurisdiction in substantially identical cases, the court hearing the second-filed action generally defers to the court hearing the first file-action."); *George Mason Univ. Found., Inc. v. Morris*, C.A. No. 11-CV-848, 2013 WL 6449109, at *4 (E.D. Va. Dec. 9, 2013) ("Under the first-to-file rule, when suits involving substantially the same parties and issues are filed in different federal courts, the federal court in which the first action is filed should decide it.") (citing *Allied-Gen. Nuclear Servs. v. Commonwealth Edison Co.*¸ 675 F.2d 610, 611 n.1 (4th Cir. 1982)).

In applying the first-to-file rule, courts in this District have looked to the "1) the chronology of the actions; 2) the similarity of the parties involved; and 3) the similarity of the issues at stake." *See, e.g.*, *Smart Techs. Inc. v. Polyvision Corp.*, C.A. No. 3:04CV545, 2004 WL 6047007, at *2 (E.D. Va. Oct. 20, 2004); *George Mason*, 2013 WL 6449109, at *4. These considerations are consistent with the Federal Circuit's goals, in applying the first-to-file rule, of "conserve[ing] judicial resources," and achieving "comprehensive disposition of litigation," while avoiding "redundancy of litigation on [the parties'] issues." *Genentech*, 998 F.2d at 938. Where the claims brought in the second-filed lawsuit are compulsory counterclaims in the first, it further bolsters the application of the first-to-file rule. *Futurewei*, 737 F.3d at 710 ("Although we rely on the first-to-file rule in affirming dismissal of [the count], our conclusion is indirectly supported by the district court's conclusion that [the count] is a compulsory counterclaim under Federal Rule of Civil Procedure 13.").[5]

[5] Those compulsory counterclaims would include Alvotech's allegations of inequitable conduct and unclean hands. While not relevant to the present motion, Alvotech's allegations rely on gross mischaracterizations of the prior art, AbbVie's patents, and their prosecution histories. Indeed, a (Continued . . .)

Here, the analysis is straightforward. The Illinois action was filed two weeks before this case. AbbVie, ABL, and Alvotech are parties to both cases. The issues to be litigated are identical: the same four patents, biosimilar product, and questions of infringement, validity, and enforceability. And Alvotech's claims could have been pursued as compulsory counterclaims in Illinois. *See* F.R.C.P. 13(a); *Unisys Corp. v. Amperif Corp.*, C.A. No. 92-1966, 1994 WL 116105, at *3 (E.D. Pa. Mar. 15, 1994) ("It is neither equitable nor acceptable for a defendant in a patent infringement case to forego[] a counterclaim for a declaration of invalidity only to assert it independently in a preferred forum."). As such, the first-to-file rule applies, and this action should be dismissed or transferred to Illinois. *Futurewei*, 737 F.3d at 708.

Alvotech's sole justification for departing from the first-to-file rule appears to be that AbbVie's Illinois suit did not include its subsidiary, Alvotech USA, which it contends was the sole "submitter" of the aBLA under the patent statute. *See* 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement to ***submit*** (C) [an aBLA] seeking approval of a biological product." (emphasis added)). That argument is both misdirected and wrong.

Alvotech's argument is misdirected: if Alvotech has a complaint about the Illinois lawsuit, it should bring it to the Illinois court. This approach comports with the general rule that questions regarding application of the first-to-file rule should be addressed by the court of the first-filed case. *API Tech. Servs., LLC v. Francis*, C.A. No. 4:13CV142, 2014 WL 12663213, at *1 (E.D. Va. Apr. 7, 2014) ("The applicability of the first-filed rule is decided by the court in which the first-filed case was brought."); *EMC Corp. v. Parallel Iron, LLC*, 914 F. Supp. 2d 125, 129 (D. Mass. 2012) ("The first-to-file rule has generally been interpreted to dictate not only which forum is

number of Alvotech's assertions have already been rejected by the Northern District of Illinois. *See In Re: Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020).

appropriate, but which forum should *decide* which forum is appropriate. Courts in nearly every circuit have held that the court in which the second action was filed should defer to courts in the first-filed action." (emphasis in original)); *Citigroup Inc. v. City Holding Co.*, 97 F. Supp. 2d 549, 557 n.4 (S.D.N.Y. 2000) ("Indeed, it is the court in which the first-filed action was brought that should decide whether an exception to the first-filed rule applies. . . . Absent such a rule, there exists the possibility of inconsistent rulings on discretionary matters as well as duplication of judicial effort." (internal cites omitted)); *Cruz v. Hartford Cas. Ins. Co.*, C.A. No. 05--38S, 2005 WL 1231965, at *3 (D.R.I. May 20, 2005) ("Thus, this Court will defer the ultimate decision on [the first to file rule] to the court sitting in the Western District of Texas[, *i.e.*, the court in which the first-filed case was brought]."); *Touchstone Rsch. Lab'y., Ltd. v. Anchor Equip. Sales, Inc.*, 294 F. Supp. 2d 823, 828 (N.D. W. Va. 2003) ("[I]t is the court in which the first-filed action was brought that should decide whether an exception to the first-filed rule applies.").

Alvotech's argument is wrong: Alvotech USA is not a submitter. And even if it were, it is not a necessary party to the Illinois litigation. To begin with, Alvotech is the submitter. The Federal Circuit has held that a party is a "submitter" for purposes of patent infringement under section 271(e)(2) if it participated in the preparation of the ANDA (or aBLA) and intends to directly benefit from the sale of the approved drug.[6] *See In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 527-29 (Fed. Cir. 2012). And "[a]n entity need not sign, prepare, or file an ANDA [or aBLA] in order to be deemed a 'submitt[er]' under Section 271(e)(2)(A)." *Otsuka Pharm. Co v. Hetero USA, Inc.*, C.A. No. CV 19-1954-LPS, 2020 WL 6822971, at *2 (D. Del. Nov. 20, 2020) (citing *Helsinn Healthcare S.A. v. Hospira, Inc.*, C.A. No. CV 15-2077 (MLC), 2016 WL 1338601, at *7

[6] While many of the cases cited herein are in the small-molecule ("Abbreviated New Drug Application" or "ANDA") context, rather than the aBLA context used for biologics, they analyze the identical issue (who is a "submitter") in the identical statutory provision (35 U.S.C. § 271(e)(2)), and are thus equally applicable.

(D.N.J. Apr. 5, 2016)). So long as a party was "'actively involved' in preparing the ANDA[or aBLA, they] are deemed to have 'submit[ted]' the ANDA [or aBLA], regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family." *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009) (quoting *Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306-07 (D. Md. 2007)).

Alvotech, not Alvotech USA, is the party that prepared the aBLA (including directing clinical trials), is responsible for manufacturing AVT02, and will benefit directly from the U.S. sales of AVT02 through its partnership with Teva. *See* Dkt. 1 at ¶¶ 20, 22; Exs. 7 and 9-14. It is therefore the "submitter" and was properly sued in Illinois.

Alvotech USA, on the other hand, is not a submitter. Given its limited responsibilities for AVT02, including its lack of participation in the development or sales of AVT02, it is not a "submitter" at all since an "entity that merely assists in collecting materials for submission to the FDA, signs the ANDA, presents the ANDA to the FDA for approval, and acts in an ongoing manner as the liaison between the FDA and the applicant during the regulatory process, but will have no involvement with the ANDA product following FDA approval, is not a submitter." *Otsuka*, 2020 WL 6822971, at *2; *see also Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, C.A. No. CV 18-73-LPS, 2019 WL 581618, *4-5 (D. Del. Feb. 13, 2019) ("What matters is the role, if any, the assisting entity [Alvotech USA] will play after the proposed product receives FDA approval. If the assisting entity will not at that point be involved in the commercial manufacture, use, or sale of the drug, then it is not a submitter.").

But even if Alvotech USA were a "submitter," the Illinois case could proceed without it. Patent infringement is a tort, and there is no requirement to name all joint tortfeasors in a single action. *Temple v. Synthes Corp.*, 498 U.S. 5, 7-8 (1990) ("It has long been the rule that it is not

necessary to join all joint tortfeasors to be named as defendants in a single lawsuit."); *Akoloutheo, LLC v. Sys. Soft Techs., Inc.*, C.A. No. 4:20-cv-985, 2021 WL 1947343 (E.D. Tex. May 14, 2021) ("Patent infringement is a tort. 35 U.S.C. § 271. It is well-settled that joint torefeasors are not considered required or indispensable parties under Rule 19." (internal quotes and cites omitted)). And even if the case were otherwise, as a wholly owned subsidiary, Alvotech USA's interests are well represented by its parent, Alvotech. *See Dainippon Screen Mfg. Co. v. CFMT, Inc.*, 142 F.3d 1266, 1272 (Fed. Cir. 1998) (finding subsidiary's interests protected by parent's participation in declaratory judgment lawsuit where they shared a "common goal"); *Extra Equipamentos E Exportacao Ltda. v. Case Corp.*, 361 F.3d 359, 364 (7th Cir. 2004) ("[W]e have great difficulty seeing how a 100 percent subsidiary could ever be an indispensable party.").

But again, the question of whether AbbVie's lawsuit in Illinois can go forward without Alvotech USA is an issue for the Illinois court to decide. Thus, this Court should exercise its "unique and substantial discretion" and decline to exercise declaratory judgment jurisdiction over this case, particularly where it is "a declaratory judgment that will serve no useful purpose." *Wilton*, 515 U.S. at 288; *see also Dunn Computer Corp. v. Loudcloud, Inc.*, 133 F. Supp. 2d 823, 8236, 829 (E.D. Va. 2001) (declining to exercise declaratory judgment jurisdiction where suit was "being used merely as a procedural device for a declaratory judgment plaintiff to select the choice of forum."). Instead, this Court should allow the Illinois court an opportunity to address that issue, reject Alvotech's attempted end run around that court's sovereignty, and dismiss this case or transfer it to the Northern District of Illinois. Alternatively, the Court would be within its discretion to stay this case pending the Illinois court's determination of the propriety of AbbVie's suit. If the Court adopts any of these options, it can stop here, and need not reach the alternative bases presented below.

B. Alternatively, This Action Should Be Dismissed for Lack of Personal Jurisdiction Under Fed. R. Civ. P. 12(b)(2)

1. Neither AbbVie Nor ABL Are Subject to General Jurisdiction Here

Neither AbbVie nor ABL is subject to general personal jurisdiction in this District. General jurisdiction exists only when a company's "affiliations with the State are so 'continuous and systematic' as to render [it] essentially at home in the forum state." *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011) (quoting *Int'l Shoe Co. v. State of Wash., Off. Of Unemployment Comp. & Placement*, 326 U.S. 310, 317 (1945)). A corporate defendant is "at home" where it is incorporated or has a principal place of business. *Daimler AG v. Bauman*, 571 U.S. 117, 138-39 (2014). But AbbVie is incorporated in Delaware, ABL is incorporated in Bermuda, and neither has a principal place of business in Virginia. Ranganathan Decl. ¶¶ 8, 13, 16.

Alvotech's only alleged basis for general jurisdiction is AbbVie's appointment of an agent for service of process in Virginia. Dkt. 1 at ¶ 57. But appointment of an agent in a forum where AbbVie is neither incorporated nor has "affiliations . . . that are so 'continuous and systematic' as to render it essentially at home" cannot form the basis for general personal jurisdiction. *See Daimler*, 571 U.S. at 138; *see also Reynolds & Reynolds Holdings, Inc. v. Data Supplies, Inc.*, 301 F. Supp. 2d 545, 551 (E.D. Va. 2004) ("[G]eneral jurisdiction over a nonresident corporation cannot be based solely on compliance with the Virginia registration statute and appointment of an agent for service of process."); *see also Ratliff v. Cooper Lab'ys., Inc.*, 444 F.2d 745, 748 (4th Cir. 1971) ("The principles of due process require a firmer foundation than mere compliance with state domestication statutes.").

2. Engaging in Required Patent Dance Exchanges Does Not Subject AbbVie or ABL to Personal Jurisdiction

Alvotech cites AbbVie and ABL's participation in the "patent dance" information exchanges under the BPCIA—a total of four communications directed to Alvotech—as a basis for personal jurisdiction. (Dkt. 1 at ¶¶ 42-46; 60.) But as Alvotech's complaint admits, the patent dance was initiated by *Alvotech*, not AbbVie. (*Id.* ¶ 44.) Alvotech USA, on behalf of Alvotech, started the dance by sending its aBLA to AbbVie's Illinois headquarters and commencing the exchange of information under the BPCIA. AbbVie was statutorily required to respond or forego its opportunity to assert its patent rights. *See* 42 U.S.C. § 262(*l*)(3)(A). Simply responding to correspondence as part of the patent dance cannot establish personal jurisdiction; otherwise, a biosimilar applicant could manufacture personal jurisdiction in the forum of its choice simply by mailing its aBLA from there. To hold otherwise, based on AbbVie' limited, and statutorily required communications with Alvotech, would not comport with "[p]rinciples of fair play and substantial justice that afford a patentee sufficient latitude to inform others of its patent rights without subjecting itself to jurisdiction in a foreign forum." *Red Wing Shoe Co. v. Hockerson-Halberstadt Inc.*, 148 F.3d 1355, 1360-61 (Fed. Cir. 1998).

3. Obtaining Patents Does Not Subject AbbVie and ABL to Personal Jurisdiction Here

The AbbVie parties also did not subject themselves to personal jurisdiction in Virginia by obtaining patents, merely because the Patent Office happens to be in Alexandria, Virginia. For example, in *Touchcom, Inc. v. Bereskin & Parr*, the Federal Circuit upheld this Court's finding of no personal jurisdiction when "appellees' contacts with Virginia were limited to the filing of a patent application at the [Patent Office] and subsequent communications and filings made in connection with that application." 574 F.3d 1403, 1412 (Fed. Cir. 2009). In doing so, the court concluded that "[w]hile appellees made such contacts purposefully . . . the contacts do not indicate

a purposeful availment of the 'privilege of conducting business within' Virginia." *Id.*; *see also Zeneca Ltd. v. Mylan Pharms., Inc.*, 173 F.3d 829, 831 (Fed. Cir. 1999) ("Under [the government contacts] exception, petitioning the national government does not 'count' as a jurisdictional contact in the personal jurisdiction analysis."); *Lismont v. Alexander Binzel Corp.*, C.A. No. 2:12-CV-592, 2013 WL 6095461, at *5 (E.D. Va. Nov. 18, 2013) (finding no personal jurisdiction based on a defendant's filing of a patent application with the PTO). If the case were otherwise, the Eastern District of Virginia would become a default forum for ***all*** patent cases.

4. Sales of HUMIRA® in this District Do Not Establish Personal Jurisdiction

Alvotech further alleges that sales of HUMIRA® and other AbbVie pharmaceutical products in this District establish personal jurisdiction. Dkt. 1 at ¶¶ 55, 62. Once again, Alvotech's theory has been rejected by the courts. As the Federal Circuit explained in *Radio Systems Corp. v. Accession, Inc.*, "only enforcement or defense efforts related to the patent ***rather than the patentee's own commercialization efforts*** are to be considered for establishing specific personal jurisdiction in a declaratory judgment action against the patentee." 638 F.3d 785, 790 (Fed. Cir. 2011). Likewise, in *Avocent*, the court explained that "in the context of an action for declaratory judgment of non-infringement, invalidity, and/or unenforceability . . . the claim asserted by the plaintiff relates to the wrongful restraint by the patentee on the free exploitation of non-infringing goods such as the threat of an infringement suit." *Avocent Huntsville Corp. v. Aten Int'l Co.*, 552 F.3d 1324, 1333 (Fed. Cir. 2008). "Such a claim neither directly arises out of nor relates to the [patentee's] making, using, offering to sell, selling, or importing of arguably infringing products in the forum." *Id.*

5. AbbVie's and ABL's Prior Lawsuits Are Irrelevant

Alvotech's reliance on two prior, unrelated lawsuits is likewise baseless. *See* Dkt. 1 at ¶¶ 56, 65. The question to be asked when a defendant has engaged in prior enforcement activities in the forum is "the extent to which the declaratory judgment claim 'arises out of or relates to those activities.'" *Avocent*, 552 F.3d at 1333 (quoting *Breckenridge Pharm. Inc. v. Metabolite Lab'ys. Inc.*, 444 F.3d 1356, 1363 (Fed. Cir. 2006)). As a result, the Federal Circuit has "(appropriately) rejected the existence of contacts concerning ***other*** patents as being pertinent to the [personal jurisdiction] minimum contacts analysis." *Xilinx, Inc. v. Papst Licensing GmbH & Co. KG*, 848 F.3d 1346, 1353 (Fed. Cir. 2017) (emphasis added).

Neither prior lawsuit cited by Alvotech involves the patents at issue here, or in AbbVie's second lawsuit against Alvotech in Illinois under the BPCIA. *See AbbVie Inc. v. Medimmune Ltd.*, C.A. No. 2:16-cv-00322-AWA-DEM (E.D. Va. June 22, 2016); *AbbVie Biotechnology Ltd v. Lee*, C.A. No. 1:12-cv-01511-AJT-TRJ (E.D. Va. Dec. 28, 2012); Yue Decl. ¶ 24; Exs. 18 &19. Further, ABL's action against the Patent Office Commissioner sought review of a patent term adjustment granted by the Patent Office, thus constituting government petitioning activity that cannot provide a basis for personal jurisdiction. *See* Ex. 19 ¶ 1; *see Mallinckrodt Med., Inc. v. Sonus Pharms., Inc.*, 989 F. Supp. 265, 271 (D.D.C. 1998) ("When instituting suit [to seek redress before the federal courts after unsuccessfully petitioning the Executive Branch], it continues to be protected by the government contacts exception."); *Zeneca*, 173 F.3d at 831 (affirming application of government contacts exception to petitioning FDA in finding Maryland courts lacked personal jurisdiction).

Alvotech also cites ABL's involvement in prior lawsuits against Amgen, Boehringer-Ingelheim, and Sandoz relating to their biosimilar HUMIRA® products. *See* Dkt. 1 at ¶ 65. But these suits are irrelevant, since they were filed in other districts (Delaware and New Jersey), and

against different parties. *See, e.g.*, *Maxchief Invs. Ltd. v. Wok & Pan, Ind., Inc.*, 909 F.3d 1134, 1138-39 (Fed. Cir. 2018) (affirming lack of personal jurisdiction over declaratory judgment defendant based on defendant's prior patent infringement suit in a different forum). The only ***relevant*** prior suit is AbbVie's pending suit against Alvotech in Illinois, on the same patents and product at issue here.

6. ABL Is Not Subject to Personal Jurisdiction Under 35 U.S.C. § 293 or Under Federal Rule of Civil Procedure 4(k)(2)

Section 293 and Rule 4(k)(2) are "savings" provisions designed to ensure that foreign entities not otherwise subject to personal jurisdiction can be sued in at least one court in the United States. *See, e.g.*, *Merial*, 681 F.3d at 1293-94. Thus, Section 293 applies only to patentees "not residing in the United States," meaning the patentee would not otherwise be subject to jurisdiction in any U.S. court. *See* 28 U.S.C. § 1391 ("[A]n entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated, shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question."). Similarly, Rule 4(k)(2) applies only to defendants "not subject to jurisdiction in any state's courts of general jurisdiction," i.e., defendants who lack sufficient jurisdictional contacts to be haled into any U.S. court.

Neither Section 293 nor Rule 4(k)(2) provide this Court personal jurisdiction over ABL because Alvotech could have sued ABL in the Northern District of Illinois, where ABL purposely availed itself of the court's jurisdiction by suing Alvotech on the same four patents, and has extensive business ties with AbbVie, including exclusively licensing the asserted patents, with the right to sue, and sending drug substance it manufactures to AbbVie's facilities in North Chicago for final packaging. *See, e.g.*, *Breckenridge*, 444 F.3d at 1366 ("[D]efendant is subject to personal jurisdiction in the forum state by virtue of its relationship with its exclusive forum state licensee if

the license agreement, for example, requires the defendant-licensor, and grants the licensee the right, to litigate infringement claims."); *Avocent*, 552 F.3d at 1335 (citing "initiating judicial or extrajudicial patent enforcement within the forum, or entering into an exclusive license agreement . . . which imposes enforcement obligations with a party residing or regularly doing business in the forum" as the basis for personal jurisdiction over defendants in connection with declaratory judgment claims of invalidity and noninfringement); Ranganathan Decl. ¶ 15. Indeed, all of the claims pleaded in Alvotech's declaratory judgment complaint would be compulsory counterclaims in AbbVie's Illinois action. F.R.C.P. 13(a); *Unisys Corp.*, 1994 WL 116105, at *3 (finding defendant's declaratory judgment claims of invalidity in a second-filed action should have been pursued as compulsory counterclaims in the first-filed action because "[i]t is neither equitable nor acceptable for a defendant in a patent infringement case to forego such a counterclaim for a declaration of invalidity only to assert it independently in a preferred forum."). ABL is thus not subject to jurisdiction under either 35 U.S.C. § 293 or F.R.C.P. 4(k)(2).

In short, personal jurisdiction is lacking over both AbbVie defendants.

C. Alternatively, This Case Should Be Transferred Under Section 28 U.S.C. § 1404(a)

Even if the first-to-file rule did not apply and jurisdiction were proper, the Court should exercise its discretion to transfer the case to the Northern District of Illinois. *See U.S. Ship Mgmt, Inc. v. Maersk Line, Ltd.*¸ 357 F. Supp. 2d 924, 935 (E.D. Va. 2005) ("The decision whether to transfer is committed to the sound discretion of the district court") (citing *S. Ry. Co. v. Madden*, 235 F.2d 198, 201 (4th Cir. 1956)); *see Old Republic Nat. Title Ins. Co. v. Transcon. Title Co.*, C.A. No. 1:07-cv-525, 2007 WL 2915171, at *3 (E.D. Va. Oct. 4, 2007) ("When a determination is made by the second filed court that the two pending actions substantially overlap, then the court

may, in its sound discretion, transfer the case to the first filed court pursuant to 28 U.S.[C.] § 1404(a).").

Section 1404(a) provides that "[f]or the convenience of the parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." Whether to transfer venue turns on two considerations: "(1) whether the claims might have been brought in the transferee forum; and (2) whether the interest of justice and convenience of the parties and witnesses justify transfer to that forum." *JTH Tax, Inc. v. Whitaker*, C.A. No. 2:07-cv-170, 2007 WL 2126300, at * 2 (E.D. Va. July 16, 2007) (quoting *JTH Tax, Inc. v. Lee*, 482 F. Supp. 2d 731, *5 (E.D. Va. 2007)); *see also Koh v. Microtek Int'l. Inc.*, 250 F. Supp. 2d 627, 630 (E.D. Va. 2003).

1. Alvotech's Declaratory Judgment Claims Should Have Been Brought in the Northern District of Illinois

Nothing would have prevented Alvotech from bringing its declaratory judgment claims in the first (Illinois) suit, which involves the same patents and product. Indeed, Alvotech's claims of invalidity, noninfringement, and inequitable conduct are compulsory counterclaims in the Illinois suit, having arisen from the same nucleus of events giving rise to AbbVie's claims. *See* Fed. R. Civ. P. 13.

Jurisdiction—both subject matter and personal—exists over Alvotech's claims in the Northern District of Illinois. Subject matter jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S. C. §§ 2201 and 2202. And personal jurisdiction exists at least by virtue of (1) AbbVie's headquarters in the district; (2) AbbVie and ABL having availed themselves of the benefits of the forum by bringing suit against Alvotech on the same four patents; and (3) ABL having engaged in exclusive licensing activities with AbbVie in connection

with the patents-in-suit and directing manufacturing activities to AbbVie's facilities in the district. *See supra* Sections II.A, III.B.6.

2. Interests of Justice and Convenience of the Parties and Witnesses Justify Transfer to the Northern District of Illinois

In considering whether "the interests of justice and convenience of the parties and witnesses justify transfer," the courts consider four factors: "(1) the plaintiff's choice of venue; (2) witness convenience and access; (3) the convenience of the parties; and (4) the interest of justice." *JTH Tax*, 2007 WL 2126300, at * 3 (citing *Bd. of Trustees, Sheet Metal Workers Nat. Fund v. Baylor Heating & Air Conditioning, Inc.*, 702 F. Supp. 1253, 1256-62 (E.D. Va. 1988)).

a. **Alvotech's choice of venue should be given little weight**

Alvotech, an Icelandic company, is the real party in interest by virtue of its role in developing and manufacturing AVT02 and the rewards it will enjoy if AVT02 is approved and marketed in the United States. *See* Exs. 7 and 9-14. It has chosen, however, to bring this lawsuit in a forum with which the parties have little connection, in terms of relevant events, witnesses, or documents. *See* Ranganathan Decl. ¶¶ 8-10, 13, 16-20, 22-24; Yue Decl. ¶¶ 31-34; Exs. 9-15, 20-24. The "[P]laintiff's choice of forum is not entitled to substantial weight if the chosen forum is not the plaintiff's 'home forum' and the cause of action bears little or no relation to the chosen forum." *Lycos, Inc. v. TiVo, Inc.*, 499 F. Supp. 2d 685, 692 (E.D. Va. 2007); *Ion Beam Applications S.A. v. Titan Corp.*, 156 F. Supp. 2d 552, 563 (E.D. Va. 2000) ("[W]here the plaintiff's choice of forum is a place where neither the plaintiff nor the defendant resides and where few or none of the events giving rise to the cause of action accrued, that plaintiff's choice loses its [] status in the court's consideration."). "Instead, if there is little connection between the claims and the chosen forum, that would militate against a plaintiff's chosen forum and weigh in favor of a transfer to a venue with more substantial contacts." *Lycos*, F. Supp. 2d at 692 (quoting *Koh v. Microtek Int'l,*

Inc. 250 F. Supp. 2d 627, 635 (E.D.Va. 2003) (internal quotes omitted). Further, the choice of forum for foreign plaintiffs is "generally given less deference, because the assumption that the chosen forum is convenient becomes 'much less reasonable.'" *NanoEntek, Inc v. Bio-Rad Lab'ys. Inc.*, C.A. No. 2:11-cv-427, 2011 WL 6023189, at *2 (E.D. Va. Dec. 2, 2011) (quoting *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 255-56 (1981)).

Moreover, the presence of Alvotech USA in Virginia should be given little weight in view of its limited presence and lack of development, manufacturing, or marketing of work for AVT02 performed in Virginia. *See Automated Tracking Sols., LLC v. Validfill, LLC,* C.A. No. 3:15-cv-142-HEH, 2015 WL 9025703, at *2 (E.D. Va. Dec. 15. 2015) (finding that the plaintiff's choice of forum was not entitled to substantial weight despite the presence of its headquarters, founder, Chief Technical Officer, and inventor of the patents-in-suit because plaintiff did not "design[], develop[], manufacture[], or sell[] any products in Virginia."); *Innovative Commc'ns Techs., Inc. v. Vivox, Inc.*, Nos. 2:12-cv-7, 2:12-cv-8, 2:12-cv-9, 2012 WL 4738979, at **3-4 (E.D. Va. Oct. 3, 2012) (declining to give Plaintiffs home forum deference despite its sole office in the district given its "tenuous" connection with the district); Dkt. 1 at ¶ 21; Ex. 15.

In addition, the material events giving rise to Alvotech's claims of invalidity and unenforceability arose outside of this District, including at AbbVie's facilities in Illinois, Massachusetts, and Germany. Ranganathan Decl. ¶¶ 17-19. Meanwhile, Alvotech's development and manufacturing of AVT02 occurred (and will continue to occur) in Iceland, not Virginia. Ex. 7. Thus, the location of the relevant underlying events disfavors Alvotech's choice of forum. *See Ion Beam*, 156 F. Supp. 2d at 563 (citing lack of events giving rise to dispute occurring in the forum in rejecting plaintiff's choice of forum).

b. **Witness convenience strongly favors Illinois**

Witness convenience strongly favors the Northern District of Illinois. AbbVie's key witnesses will include the inventors of the asserted patents, who will testify about their work in developing their patented inventions. To the best of AbbVie's knowledge, none reside in Virginia, whereas many (including John Medich, Wolfgang Fraunhofer, Thomas Harris, Rebecca Hoffman, Mark Weinberg, and Phillip Yan) reside in Illinois, and others (Hartmut Kupper, Hans-Juergen Krause, Markus Tschoepe, Katharina Kaleta, and Annika Bartl) reside in Germany, where AbbVie has a research facility. Ranganathan Decl. ¶¶ 22-24; Exs. 20-23 . The remaining inventors (Robert Wong, Elliott Chartash, Steven Fischkoff, Lori Taylor, and George Granneman) are located in New Jersey, Boston, or Florida. Ex. 24; Yue Decl. ¶¶ 31-34.

In addition to the inventors, given its center of gravity in Illinois, AbbVie will have numerous other witnesses there, including, for example, Rule 30(b)(6) witnesses on topics like its sales and marketing of HUMIRA®, and the long felt need for the inventions embodied by these patents. Ranganathan Decl. ¶ 10.

Further, a number of AbbVie's Illinois witnesses (including Harris, Hoffman, Weinberg, and Yan) are not employed by AbbVie. *See* Exs. 20-23. Their convenience as third-party witnesses is given particular weight. *See, e.g.*, *Nunes v. WP Co., LLC,* C.A. No. 3:20-cv-146, 2020 WL 2616707, at *4 (E.D. Va. May 22, 2020) ("The convenience of witnesses is of considerable importance when considering a transfer, especially the convenience of non-party witnesses, whose location should be afforded greater weight in deciding a motion to transfer venue."). In addition, AbbVie's key documents relating to the work underlying the asserted patents and the commercial success of HUMIRA® (relevant to patent validity) are not located in Virginia. Ranganathan Decl. ¶ 20.

Meanwhile, because AVT02 was developed and manufactured in Iceland, the vast majority of Alvotech's relevant witnesses will be located there. Exs. 7 & 26-27. Alvotech also conducted clinical trials in Australia, New Zealand, and several European countries, including Russia, Poland, and the Ukraine. Exs. 9-14. While Alvotech USA has a small office in this District, in view of the subsidiary's limited administrative functions, *see* Dkt. 1 at ¶ 21, it is unlikely any material witnesses are located in this District. Likewise, AbbVie expects that the relevant documents relating to Alvotech's infringement of AbbVie's patents are primarily located in Iceland, not Virginia.

Finally, the witnesses not located in the Northern District of Illinois, for example in Germany or Iceland, can get to the Northern District of Illinois (e.g., via O'Hare International Airport) at least as easily as they can get to this Court.

Witness convenience strongly favors transfer to the Northern District of Illinois.

c. **Convenience of the parties favors Illinois**

While this factor is given less weight, it too favors the Northern District of Illinois. AbbVie (and its predecessor) have been headquartered in North Chicago for nearly 100 years. Ranganathan Decl. ¶ 8. Alvotech is in Iceland, and therefore is neutral in the analysis. Ex. 15. And while Alvotech USA is in Virginia, it was founded only two years ago, and has minimal, if any, involvement in the substantive issues raised by Alvotech's declaratory judgment claims. *See* Dkt. 1 at ¶ 21; Ex. 15.

d. **The interests of justice favor Illinois**

In assessing the interests of justice, courts consider judicial economy, the potential for inconsistent results, and attempts to manipulate the federal system through forum shopping. The interest of justice is primarily concerned with systemic integrity and fairness. *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22, 30-31 (1988). Those interests also favor Illinois.

AbbVie has already sued Alvotech in the Northern District of Illinois, where the same issues of infringement and validity for the same four patents and the same product will be vigorously litigated. And there is now another patent suit in that district, involving the same product and related patents. Transferring this Illinois will facilitate judicial economy and avoid inconsistent rulings. Further, the Northern District of Illinois has an interest in hearing a case involving a party that employs over 10,000 people in Illinois and has been there a century.

Considerations of systemic integrity, particularly Alvotech's filing in contravention of the first-to-file rule and basic fairness, also favor transfer to Illinois. Alvotech's strategy is self-evident: force AbbVie to litigate its BPCIA lawsuit in this District, where it has no corporate presence, none of its witnesses are located, and none of the events underlying the issues to be litigated occurred, rather than at home. Alvotech's jurisdictional gamesmanship should be rejected, and the case transferred to the Northern District of Illinois.

IV. CONCLUSION

For the foregoing reasons, AbbVie respectfully requests that the Court grant the motion to dismiss under the first-to-file rule and principles of federal comity or Fed. R. Civ. P. 12(b)(2); or, in the alternative, transfer the case to the Northern District of Illinois under 28 U.S.C. § 1404(a).

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